Attorney's Docket No.: 09010-005009 / DIVER1130-8

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Short, et al. Art Unit: 1652

Serial No.: 09/966,803 Examiner: Delia M. Ramirez, Ph.D.

Filed: September 27, 2001

Title : ENZYMES HAVING AMIDASE ACTIVITY AND METHODS OF USE

THEREOF

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

- 1. I, Jay Short, am an expert in the field of molecular biology and enzyme development and was an expert at the time of the invention. I am presently employed as CEO and as a research scientist at Diversa Corporation, San Diego, CA, assignee of the above-referenced patent application. My resume is attached as documentation of my credentials.
- 2. I declare that the state of the art at the time of the invention and the level of skill of the person of ordinary skill in the art, e.g., procedures for screening enzymes and for screening nucleic acids encoding enzymes, e.g., for amidase activity, was very high. Using the teaching of the specification, one skilled in the art could have selected routine methods known in the art at the time of the invention to express variants of nucleic acids encoding the exemplary amidase enzyme of the invention and screen them for expression of polypeptides having amidase activity. One skilled in the art could have used routine protocols known in the art at the time of the invention, including those described in the instant specification, to screen for nucleic acids encoding polypeptides having a percent sequence identity to SEQ ID NO:1, or active fragments thereof, for amidase activity. At the time of the invention it was routine to screen for multiple substitutions or multiple modifications of an enzyme-encoding sequence and predictably achieve positive results. While the numbers of samples needed to be screened may have been high, the screening procedures were routine and successful results (i.e., finding variant nucleic acids encoding amidases) predictable. Furthermore, it would not have required any knowledge or guidance as to which are the specific structural elements, e.g., amino acid residues, that correlate

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with amidase activity to create variants of the exemplary nucleic acid and test them for the expression of polypeptides or peptides having amidase activity. Accordingly, it would not have taken undue experimentation to make and use the claimed invention, including identification of a genus of nucleic acids encoding amidases active under various conditions.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted

Date: 2/10/2004

Jay Short